

K132963
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FusionSync

510(k) SUMMARY
Traditional Premarket Notification 510(k)

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DEC 16 2013



510(k) summary of safety and effectiveness (21 CFR 807.92):

Date of summary: 08/08/2013
807.92(a)(1)

Owner/Submitter's name: Chimaera GmbH
807.92(a)(1)

Owner/Submitter's address: Am Weichselgarten 7,
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Device Proprietary Names: FusionSync 1.0
807.92(a)(2) Chimaera FusionSync 1.0

Device Common Name(s): Multi-modality Registration Software
807.92(a)(2)

Classification Name: Class II: Picture Archiving and Communications System
807.92(a)(2) (892.2050) Product Code: **LLZ Image Processing System**

807.92(a)(3):

FusionSync is Substantially Equivalent to the following Legally Marketed device:

| 510(k) Number | Trade Name | Manufacturer |
|---------------|------------|---------------------|
| K020546 | Fusion7D | Mirada Medical Ltd. |

Definitions:

| | |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Image Registration | The alignment of one or more images to a reference image. The alignment is computed based on a mathematical optimization problem that spatially correlates the images according functional activity or anatomical structures. The result of a registration is a transform that describes the spatial |
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| | correlation of 3D positions between the images. |
| Image Fusion | Visualize the content of different images (usually the same organ or anatomical region) in the same image viewer window. A common technique is to overlay the different images via semi-transparent rendering. |
| Synchronization/ Binding | Spatial linking of two different image views (no overlay), as for example Multiplanar Reconstruction (MPR) views. The registration transform builds the spatial link between two series such that the visualization setting (e.g. spatial orientation and position) of one MPR view is transferred to a linked MPR view such that both views show the same anatomical region during navigation of one of the MPRs through the volumetric data. |

1 DEVICE DESCRIPTION (807.92(a)(4))

Labeling Description Example:

Today, diagnosis based on follow-up image series and multi-modal acquisitions is often time-consuming due to missing data alignment and the need for manual adaptations of viewing settings. **FusionSync** is a fast, automatic image-registration algorithm that is seamlessly integrated in the aycan workstation OsiriX.PRO. **FusionSync** allows viewing of multi-modal and follow-up series together. Users can navigate easily through large data sets based on spatial synchronization. Time-consuming adaptations of view settings are completely eliminated, as viewing properties are propagated to all linked series.

Device Description:

FusionSync is a software program that provides a registration engine to align (register) pairs of images from same and different imaging modalities. The platform-independent registration engine is designed as a plug-in component that has the ability to extend the productivity of existing viewers like CAD workstations or PACS. The graphical user interface of **FusionSync** is designed as a plug-in component for aycan workstation OsiriX.PRO. It includes functionality to display the original volumetric data and the results of the registration operation. The graphical user interface allows to control the registration engine and fusion visualization.

Registration Engine:

FusionSync supports the registration of anatomical images (MRI and CT) and functional images (SPECT and PET). The registration engine provides a) manual registration, where the user defines the registration transform and b) automatic registration, where the software computes without any user input the registration result. The transformation is limited to a rigid body deformation (i.e. translation and rotation). The registration engine allows to register any combination of CT, conventional MRI, PET and SPECT images. The advanced technology of our registration engine is designed to easily and rapidly integrate into existing medical imaging applications.

2 INTENDED USE (807.92(a)(5))

The device **FusionSync** contains automatic registration algorithms that are intended for the spatial

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synchronization of different series. The automatic algorithm is not intended for the registration of series from modalities other than: CT, conventional MRI, PET or SPECT. In addition, the product contains a manual mode (non-automatic) that allows the registration via user interaction such that for example automatic registration results can be refined. The intended clinical use is to display different 3D series from the same patient in spatial synchronization as for example, but not limited to, follow-up examinations. The displayed series can be visualized as MPR views with arbitrary 3D orientation. It is possible to overlay a registered series onto an MPR view. The spatial synchronization and optional overlay, based on the registration result, is intended to help the clinician to obtain a better understanding of the joint information of two registered images. The clinician retains the responsibility for making the diagnosis based on their standard procedures where the separate unregistered images are compared visually. **FusionSync** complements these clinical standard procedures.

3 TECHNOLOGICAL CHARACTERISTICS/FEATURE COMPARISON

807.92(a)(6):

The following Table 1 provides technological characteristics and a feature comparison to the predicate device:

| Feature | Fusion7D | FusionSync |
|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-----------------------------------------------|
| <i>Registration Engine</i> | | |
| Automatic Registration | YES | YES |
| Manual Registration | YES | YES |
| Semi-automatic (matching of landmarks) | YES | NO |
| Rigid body deformation i.e. translation and rotation | YES | YES |
| Consecutive sequence of fusion methods. (An automatic fusion can be run on the results of an initial step e.g. manual registration) | YES | YES |
| Fast Registration | 20-30s even for very large imaging studies. | 3-10s even for very large imaging studies. |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------|-----|
| Spatial Precision 1. Precision depends on the accuracy of the lowest resolution voxel in either the source or target imaging study. 2. For high resolution CT or MRI the fusion should achieve millimeter-level accuracy 3. Lower resolution data sets for functional imaging typically have a voxel resolution of several millimeters (even centimeters in the slicing direction) | | YES | YES |
| Deformable body deformation i.e. non-rigid registration | | YES (Fusion7D Advanced) NO (Fusion7D Standard) | NO |
| Supported data to compare pairs of images: <i>Anatomical to Anatomical</i> | | | |
| Source | Target | | |
| MRI | MRI | YES | YES |
| MRI | CT | YES | YES |
| CT | CT | YES | YES |
| <i>Anatomical to Functional</i> | | | |
| Source | Target | | |
| MRI | PET | YES | YES |
| MRI | SPECT | YES | YES |
| CT | PET | YES | YES |
| CT | SPECT | YES | YES |
| <i>Data/Image Browsing and Visualization</i> | | | |
| Orthogonal and any-plane slicing of the volumetric data | | YES | YES |
| Whole and region of interest zooming | | YES | YES |
| Panning | | YES | YES |
| Window and level controls | | YES | YES |
| Image overlays for which the transparency, threshold and colormap is user controlled | | YES | YES |

| | | |
|------------------------------------------------------------------------------------------|-----------------------------|-----------------------------|
| Bindings/Spatial Synchronization (using tools such as Zoom affect every image window) | YES | YES |
| Save/Load Transformation (registration matrix) | YES | NO |
| Live Updates (shows on the screen the steps in the registration process) | YES | NO |
| Stand-Alone Workstation Software | YES | NO |
| Application Range | Radiology, Nuclear Medicine | Radiology, Nuclear Medicine |
| Supports compressed image formats | NO | NO |
| Snapshot (capture any image) | YES | YES |

Table 2: Comparison of technological features

3.a SUMMARY

FusionSync does not provide landmark based registration. However, this feature requires the user to manually place software based landmarks in the rendered images. This is very time consuming and usually a feature that is rarely used in standard clinical routines. It is sufficient to provide a manual registration to allow a physician a refinement/correction of an automatic registration result. Furthermore, **FusionSync** does not feature a live update of the fused images during the registration process. This does not effect the effectiveness of the device since there is no diagnostic benefit from showing intermediate results of a registration that takes in average less than three seconds.

4 DISCUSSION OF NON-CLINICAL TESTS PERFORMED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

807.92(b)(1):

Performance testing included software validation, verification and testing per FDA's software validation guidance.

5 DISCUSSION OF CLINICAL TESTS PERFORMED

807.92(b)(2): N/A

6 SUMMARY AND CONCLUSIONS

807.92(b)(3):

The intended use, technological characteristics/features and performance characteristics for **FusionSync** are substantially equivalent to the legally marketed predicate device Fusion7D. The documentation supplied demonstrates that any difference in technological characteristics do not raise

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any new question of safety or effectiveness.

The 510(k) Pre-Market Notification for **FusionSync** contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

The submission contains the results of a hazard analysis and the “Level of Concern” for potential hazards has been classified as “Moderate”.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

Chimaera GmbH
% Marcus Pruemmer, Dr.-Ing, CEO
Am Weichselgarten 7
Erlangen, Bavaria, 91058
GERMANY

Re: K132963

Trade/Device Name: FusionSync, Chimaera FusionSync
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications software
Regulatory Class: Class II
Product Code: LLZ
Dated: September 26, 2013
Received: September 27, 2013

Dear Dr. Pruemmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

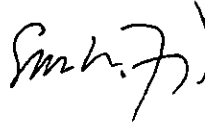
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2—Dr. Pruemmer

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K132963

Device Name
FusionSync

Indications for Use (Describe)

The device FusionSync contains automatic registration algorithms that are intended for the spatial synchronization of different series. The automatic algorithm is not intended for the registration of series from modalities other than: CT, conventional MRI, PET or SPECT. In addition, the product contains a manual mode (non-automatic) that allows the registration via user interaction such that for example automatic registration results can be refined. The intended clinical use is to display different 3D series from the same patient in spatial synchronization as for example, but not limited to, followup examinations. The displayed series can be visualized as MPR views with arbitrary 3D orientation. It is possible to overlay a registered series onto an MPR view. The spatial synchronization and optional overlay, based on the registration result, is intended to help the clinician to obtain a better understanding of the joint information of two registered images. The clinician retains the responsibility for making the diagnosis based on their standard procedures where the separate unregistered images are compared visually. FusionSync complements these clinical standard procedures.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

